Remarks

Claims 1-14 are pending in the present application and stand rejected.

Claims 1-14 are rejected as indefinite under 35 U.S.C. §112. In particular, the examiner objects to recitation of the phrase "antigenic fragment thereof," stating the opinion that the intended fragment is not defined and the specification teaches only a construct using ubiquitin and an intact gene. Applicants traverse this rejection.

The phrase "antigen fragment" is defined in the specification as including CTL epitopes from the protein and portions of the protein that contain such epitopes. Applicants would like to specifically point to paragraph 54 of the specification which describes and defines the term "antigen fragment." Applicants submit that no skilled person would be unclear regarding the metes and bounds of this term, especially given the well-studied nature of the proteins in question and their antigenicity. Additional guidance with respect to fragments and antigen-encoding sequences is provided in paragraphs 73-74, 81 and 83, for example. Specific examples include gB(s), IE1 exon 4, and NLVPMVATV, which are described at length. Therefore Applicants respectfully submit that the Office Action is not correct when stating that only intact genes are disclosed. See also Example 2. Therefore, Applicants submit that fragments are described, enabled and are not indefinite since the proteins pp65, pp150, IE1 and gB are well described in the art and the skilled person can determine what are the CTL epitopes of the proteins from studying the literature and referring to the specification here. One of skill in the art would understand from the disclosures of the specification that

any protein or peptide sequence that encodes a CTL epitope, regardless of length and including the entire protein sequence, would be processed by a cell to display the CTL epitopes in the context of the appropriate HLA antigen. No skilled person would be confused as to what is meant by an antigenic fragment in this case. Applicants therefore request reconsideration and withdrawal of this rejection.

Claims 1-4 and 6 are rejected as anticipated under 35 U.S.C. §102(a) by Paoletti et al. This reference is cited as teaching expression of cytomegalovirus proteins, including pp65, pp150, IE1, and gB, using poxvirus vectors in general and NYVAC and ALVAC in particular. Paoletti et al. discuss modified recombinant viruses that include DNA encoding one or more HCMV antigen or epitope, including gB, pp150, pp65 and IE1 and altered versions of IE1 and gB, but does not disclose MVA as stated in the Office Action at page 4, lines 13-14. Claim 1 has been amended to incorporate the features of claims 3 and 5, and now recites that the virus vector is Modified Vaccinia Ankara. Claim 6, here rejected, already recites this feature.

In order to make out a case of anticipation, the Office must show that the cited reference contains each and every limitation of the claims within its four corners. Here, the Office Action concedes that the reference lacks at least one feature of the amended claims. Applicants therefore request that this rejection be withdrawn as improper in view of the amendments to claim 1.

Claims 1-4, and 6-14 are rejected under 35 U.S.C. §102(a) as anticipated by La Rosa et al., which is cited for teaching a fusion of cytomegalovirus genes to human ubiquitin gene and a construct inducing an enhanced immune response in mice. This reference is co-authored by the inventor of the present application, Dr. Don Diamond. It is Applicant's intention to

antedate this reference. However, Applicants would like to point out that the LaRosa article does not teach the limitations of claim 5, which is not rejected here. These features have been incorporated into claim 1, and claim 6 already recites a Modified Vaccinia Ankara viral-vector as discussed above.

Applicants therefore submit that the rejection is not proper against the amended claims and should be withdrawn.

Claim 1-4 and 6 are again rejected, this time under 35 U.S.C. §102(e), as anticipated by Paoletti et al. Applicants refer the Office to the discussion above regarding anticipation by Paoletti et al. and submit that this rejection also is obviated. Applicants request this rejection be withdrawn.

Claims 1-6 are rejected under 35 U.S.C. §103(a) as obvious over the combination of Paoletti et al. and Sutter et al. Applicants traverse this rejection. The disclosures of Paoletti et al. have been discussed above. The second reference, Sutter et al. is cited for teaching that MVA can be used to express foreign genes for vaccine use. The combination of Paoletti et al. and Sutter et al. therefore are cited as teaching an MVA expression vector suitable for expressing the antigens discussed above.

To make out a prima facie case of obviousness against a claim, the Office is obligated to show that all three of the following conditions are met: (1) the cited references teach or suggest every limitation of the rejected claim, (2) there is specific motivation to combine and/or modify the cited teachings and suggestions to achieve what is claimed, and (3) there is a reasonable expectation of success. Failure to meet even one of these criteria is fatal to the Office's case.

The Office Action does not refer to any specific motivation in the cited references but only concludes that it exists. For

this reason alone, the rejection should be withdrawn pending such a showing. However, there is no specific motivation to achieve what is claimed here in the cited references. The Office Action states that the Sutter et al. reference teaches MVA as a "general" expression vector. Such a teaching is not a specific motivation to achieve the specific invention of the claims, especially since there is no indication in any of the references that success could be achieved in this manner to make a vaccine vector. Applicants submit that the Office has failed to show sufficient specific motivation or reasonable expectation of success in making out its prima facie case of obviousness. Applicants therefore request reconsideration and withdrawal of this rejection.

Claims 1-14 are rejected under 35 U.S.C. §103(a) as obvious over La Rosa et al. and Sutter et al. La Rosa et al. is cited for teaching fusion of cytomegalovirus genes to the human ubiquitin gene for enhanced immune responses in mice. Sutter et al. is cited for teaching Modified Vaccinia Ankara Virus for expression of foreign antigen. The examiner concludes from these asserted teachings that one of ordinary skill in the art would have found it obvious to use the expression vector of Sutter et al. to express the La Rosa construct.

Applicants submit that the Office has not shown here any specific motivation to achieve the invention which is claimed in the cited art, only an asserted general similarity of the vectors which, contrary to the Office Action, is not a motivation to make the specific MVA vector and construct which is claimed here. For the reasons discussed above, therefore, Applicants request reconsideration and withdrawal of this rejection.

Applicants request reconsideration of the application as a whole, withdrawal of the rejections, and allowance of the amended claims.

Respectfully submitted,

By _____

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